

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC.,

Plaintiff,

V.

MSN LABORATORIES PRIVATE LIMITED
and MSN PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 19-2017 (RGA) (SRF)
CONSOLIDATED

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**OPPOSITION LETTER TO THE HONORABLE SHERRY R. FALLON
REGARDING EXELIXIS' REQUEST TO MODIFY THE PROTECTIVE ORDER**

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Dear Judge Fallon:

This firm, along with Winston & Strawn LLP, represents MSN and respectfully submits this opposition to Exelixis' motion to modify the Stipulated Protective Order. Exelixis improperly seeks that modification to prevent Dr. Kondal Reddy Bairy from accessing information the Court already said he is permitted to access and for which there is only a low risk of inadvertent disclosure. Exelixis has not challenged the factual bases for those findings, and nothing has changed since the Court's July 14 Order (D.I. 162): The same individual is seeking access based on the same circumstances. Exelixis provides no reason to revisit that order beyond its general dislike of it. Exelixis' failure to identify any actual errors in the July 14 Order means it should not succeed on this request to modify.

I. Procedural history

The Court ruled in the July 14 Order that MSN's sole in-house designee, Dr. Bairy, can access Exelixis' confidential information in accordance with the terms of the parties' Stipulated Protective Order. The July 14 Order recognizes that this includes access to information regarding Exelixis' "[h]ighly proprietary manufacturing process for cabozantinib-(s)-malate and the controls it employs to ensure the polymorphic form of cabozantinib-(s)-malate allegedly used in the accused product does not convert to another form." D.I. 162 at ¶¶ 1, 8. The Court reached that conclusion after correctly finding that Dr. Bairy is not a competitive decision-maker, that he is not involved in research and development of the accused ANDA Product, and that "the risk of inadvertent disclosure is low." D.I. 162 at ¶¶ 4, 5, 7. The Court also found that the harm to MSN from Exelixis' proposed restrictions "is significant" because "Dr. Bairy is the only employee coordinating on this litigation with outside counsel." *Id.* at ¶¶ 3, 7.

Exelixis then asked MSN to agree to certain modifications to the Protective Order that are more restrictive than those contemplated by the July 14 Order. Its request was based in part on the definition of "Highly Confidential Information" in litigation over an unrelated drug in an unrelated case. C.A. No. 20-1105 (Consolidated), D.I. 56. *See* D.I. 188, Ex. C at 36 (2021.7.15 email from K. Prussia). Though under no obligation to do so, MSN agreed to additional restrictions that *exactly* mirror those it agreed to in that case. *See* C.A. No. 20-1105 (Consolidated). But MSN's agreement to terms consistent with that other order did not satisfy Exelixis. Contrary to the July 14 Order, Exelixis demanded that MSN submit to restrictions that MSN did not agree to in the other case and does not agree to here: that Dr. Bairy give up access to discovery concerning "(i) the processes for making cabozantinib forms, (ii) methods, techniques, or controls used to prevent or identify conversion from one form to another, (iii) performance data for cabozantinib forms, and (iv) non-public information for cabozantinib forms other than the L-malate salt." (D.I. 174 at 1; *see also* D.I. 188, Ex. A at 4.) Meanwhile, Exelixis' own in-house designee would continue to have access to MSN's proprietary process for making cabozantinib. (D.I. 188, Ex. A at 2 n. 1.) Dr. Bairy has thus been precluded from participation in several fact depositions that related directly to MSN's articulated defenses of non-infringement and invalidity of two of the four patents in suit, while Exelixis' in-house designee has been present at most of the depositions of MSN witnesses.

In now seeking to modify the Protective Order to add that disputed restriction, Exelixis

does not challenge the Court's findings that Dr. Bairy is not a competitive decision maker or that the risk of inadvertent disclosure by him is low. Exelixis argues in substance only that disclosure of the disputed information to Dr. Bairy is not necessary, and that its inadvertent disclosure might damage Exelixis. The first argument is legally and factually inaccurate. The information to which MSN seeks access is relevant to core defenses in this case, as explained further below. And the argument that Exelixis might be damaged by inadvertent disclosure has already been addressed. The risk is very low because, as discussed below, it could not realistically happen. At the very least, the risk is no more than the risk of Exelixis' designee's harmful potential disclosure of MSN confidential information to which they already have access.

II. Legal standard

Exelixis "bears the burden of demonstrating good cause" to modify the Protective Order. *Apeldyn Corp. v. AU Optronics Corp.*, 2012 WL 2366537, at *1 (D. Del. June 20, 2012). "Good cause is established on a showing that disclosure will work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994). What matters most is whether the employee is "involved in competitive decision making of the company and [the Court] should examine the risks and safeguards surrounding inadvertent disclosure" *Affymetrix, Inc. v. Illumina, Inc.*, 2005 WL 1801683, at *2 (D. Del. July 28, 2005) (citing *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 (Fed. Cir. 1984)). In considering motions to modify protective orders, Third Circuit courts also look at "the reliance by the original parties on the confidentiality order." *Pansy*, 23 F.3d at 790. Because no one disputes that Dr. Bairy is *not* a competitive decision-maker and the risk of inadvertent disclosure is low, there is no good cause to modify the protective order under these standards.

III. Argument

A. MSN would be harmed if Dr. Bairy's access is further limited.

Dr. Bairy's responsibility for overseeing the conduct of this litigation requires him to fully evaluate the strength of MSN's invalidity and noninfringement defenses. That need requires him to have access to the disputed Exelixis confidential information, solely for purposes of defending against Exelixis' infringement charges.

For instance, the portions of the [REDACTED] that Exelixis would preclude Dr. Bairy from accessing includes a host of experimental results showing that [REDACTED]

[REDACTED] See D.I. 188, Ex. H at EXEL_00068801, 808–09. Exelixis also now seeks to redact all the [REDACTED]

[REDACTED] In other words, Exelixis is trying to conceal from Dr. Bairy the facts surrounding its spend of millions of dollars and years of advanced research to [REDACTED]. See, e.g., D.I. 188, Ex. J at EXEL_00022384 (describing the "Control of Crystal Form"). The very notion that Exelixis spent such significant resources [REDACTED] strongly suggests that those inventions are not inventive but are instead obvious and the natural result of routine work. As of now, MSN's outside counsel cannot discuss *any* of these facts with Dr. Bairy.

Exelixis contends that its “internal, non-public information is not prior art” and thus not relevant to the obviousness defense. D.I. 188, Exelixis’ Letter (“Ltr.”) at 4. But this information—whether public prior art or not—is relevant because it shows that [REDACTED] *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364, 1367 (“[C]onsideration of the ‘routine testing’ performed by Pfizer is appropriate.”) (citation omitted). In other words, the law holds that Exelixis is not entitled to a patent for [REDACTED] that the evidence shows result from many standard experimental techniques a person of ordinary skill in the art would employ.

Regarding MSN’s defenses under 35 U.S.C. § 112, Exelixis’ redactions to the [REDACTED] describe experiments and analysis that show the inventors were never [REDACTED]

[REDACTED] See D.I. 188, Ex. H at EXEL_00068793–800. Exelixis also intends to redact the only analytical technique it uses to [REDACTED]

[REDACTED] Ltr. at 4; see D.I. 188, Ex. I at EXEL_00050769. Again, MSN’s counsel cannot discuss these facts with Dr. Bairy at this point, despite their clear relevance to several defenses.

Exelixis suggests that Dr. Bairy can properly advise on litigation strategy without seeing protected information. But MSN plans to supplement its contentions in accordance with the case schedule to add information obtained from these documents and related deposition testimony during fact discovery. Further, it is likely that MSN’s experts may discuss this same information in forthcoming expert reports. Dr. Bairy must be able to review full copies of MSN’s contentions and expert reports, because that is information that will very likely be presented at trial.

Exelixis next cites the protective orders in the *Biogen* and *Takeda* cases to argue that Dr. Bairy does not need access to the disputed information here. But Exelixis was not a party to those cases and could not know that MSN agreed to such protective orders because access to restricted information was not necessary to fully defend those cases. That is a different situation from this one, where the active ingredient and its polymorphic form is at the heart of the case.

MSN also relied on the current version of the protective order, which weighs against modification. Dr. Bairy stated in his declaration that he “reviewed and authorized the agreement to stipulate to the Protective Order.” D.I. 159, Ex. 1, at ¶ 4. He also said that “[b]ecause MSN has no in-house attorneys and my role requires me to have access to patentee’s information to assess litigation strategy, I would not have agreed to this Protective Order if I believed it would be interpreted to limit access to only attorneys or those who are supervised by attorneys.” *Id.* Exelixis certainly agrees that the individuals overseeing the litigation should have access to the other side’s protected information. Its in-house counsel has been present at the depositions of numerous MSN witnesses who testified about MSN’s most highly confidential information related to its ANDA product and processes for making it.

In sum, Dr. Bairy explained in his declaration that he has “ultimate authority for all decisions related to the conduct of litigations in which MSN is currently involved.” D.I. 159, Ex.

1, at ¶ 3. Courts have found that “the more [in-house designees’] roles have been limited to the conduct and settling of litigation, and the less they have been engaged in regular direct contact with the company’s decisionmakers, the more likely the courts have been to find that the attorneys could have access to confidential information without undue risk of inadvertent disclosure.” *Brit. Telecommunications PLC v. IAC/InterActiveCorp*, 330 F.R.D. 387, 393 (D. Del. 2019) (Bryson, J.) (citing cases). This case should be no different, especially in light of the fact that Exelixis’ General Counsel has access to all of MSN’s confidential information.

B. Exelixis would not be harmed by Dr. Bairy’s access.

The record also makes clear that there is no realistic risk of harm to Exelixis if Dr. Bairy maintains the access the Court granted in the July 14 Order. Dr. Bairy’s role differs significantly from those of the competitive decision-makers in the cases cited by Exelixis. *See, e.g., PhishMe, Inc. v. Wombat Sec. Techs., Inc.*, 2017 WL 4138961, at *4–6 (D. Del. Sept. 18, 2017) (denying General Counsel access because he was a competitive decision-maker who directly advised the CEO); *Safe Flight Instrument Corp. v. Sundstrand Data Control Inc.*, 682 F.Supp. 20, 21–22 (D. Del. 1988) (denying access to the patentee’s president, who was also the inventor on over 60 patents and a “preeminent” engineer actively involved in research and development). Exelixis’ statement that MSN litigated this case without Dr. Bairy seeking access until now actually shows the seriousness with which MSN has treated Exelixis’ protected information. Dr. Bairy waited until depositions to seek access because he did not need full details of the defenses before then.

Exelixis nevertheless alleges that its “trade secrets could be leveraged in the development of competing products.” Ltr. at 3. The allegation makes no sense. [REDACTED]

[REDACTED] that Exelixis all but admits is different from [REDACTED] MSN made that noninfringing polymorph with no access at all to Exelixis confidential information. Thus, in order for Exelixis to be harmed according to the lone example it provides— [REDACTED]

[REDACTED]—Dr. Bairy would need to blatantly violate the protective order and disclose entire sections of the NDA to MSN scientists in India. Those scientists would then need to change MSN’s already established manufacturing process for the ANDA product at issue, as well as create and test new batches to validate the process before re-seeking FDA approval. All of these changes would of course need to take place against the backdrop of [REDACTED]

[REDACTED]. The risk of such an egregious violation is extremely low, if not inconceivable.

Exelixis’ position is also disingenuous because it has designated its own General Counsel, a member of the Exelixis executive team whose responsibilities reach beyond overseeing individual litigation, to have full access to MSN’s most valuable confidential information in this case. In fact, that designee reports directly to the CEO, who oversees *everything* Exelixis does. If the low risk of inadvertent disclosure of MSN information by Exelixis’ designee is acceptable, then the low risk of inadvertent disclosure of Exelixis information by Dr. Bairy is also acceptable.

MSN thus respectfully requests that the Court deny Exelixis’ motion.

Respectfully,

/s/ Dominick T. Gattuso

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